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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,324	12/16/2003	Edward H. Cully	MP/179	5934
28596	7590	04/03/2007	EXAMINER	
GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/03/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/737,324	CULLY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	DAVID J. ISABELLA	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 12 January 2007.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1,3-13,15-19,21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 25-28 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-6,8-13,15-19,21,23,24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 1/12/2007.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

***Status of the Claims***

Amendment filed on 1/12/2007 amends claims 1,21,23,24. Claims 2,14,20,22 and 29-34 remain cancelled. Claims 7 and 25-28 remain withdrawn from consideration as being drawn to non-elected species. Accordingly, claims 1,3-6,8-13,15-19,21,23 and 24 are pending for consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The combination of means for splitting including reduced thickness or a row of perforations in combination with anisotropic material is not supported by applicant's specification. Examiner has reproduced the portion of the specification pertaining to the anisotropic material as set forth in applicant's specification. Applicant sets forth the embodiment for using a tape that is helically wrapped about the stent.

Figure 4C shows a device 10 wherein a graft material 18 is provided having a node 42 and fibril 44 microstructure (e.g., ePTFE), of which a small sample area 18el is shown enlarged. This graft material 18 is oriented so as to be weaker in the longitudinal direction than in the radial (circumferential) direction. The

ePTFE microstructure shown has a uniaxial microstructure, meaning that the fibrils are oriented primarily in a single direction. The graft material is thus amenable to splitting in the same direction as its direction of greatest strength (i.e., the direction of orientation of the fibrils). This orientation allows for the possibility of the graft material 18 splitting or separating between adjacent windings of the stent component 14 during removal of the stent in the manner previously described (i.e., cohesively disassembling). A preferred method of using such a node and fibril microstructure graft material is to use a film such as an ePTFE film, that has been cut into a long, narrow tape with the length of the tape parallel to the direction of the fibrils. This tape can be used as a graft covering either over or beneath the stent component 14, or both over and beneath stent component 14, and is applied as a helical wrap with the pitch of the helix equal to and parallel to that of the helical pitch of the serpentine stent wire. This allows for disruption of the graft material 18 parallel to the pitch of the serpentine stent winding 14, by splitting of the tape parallel to its length (i.e., parallel to the direction of the fibrils) during stent removal, generally as shown by Figure 2

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 4 depend from cancelled claim 2.

### ***Claim Rejections - 35 USC § 102***

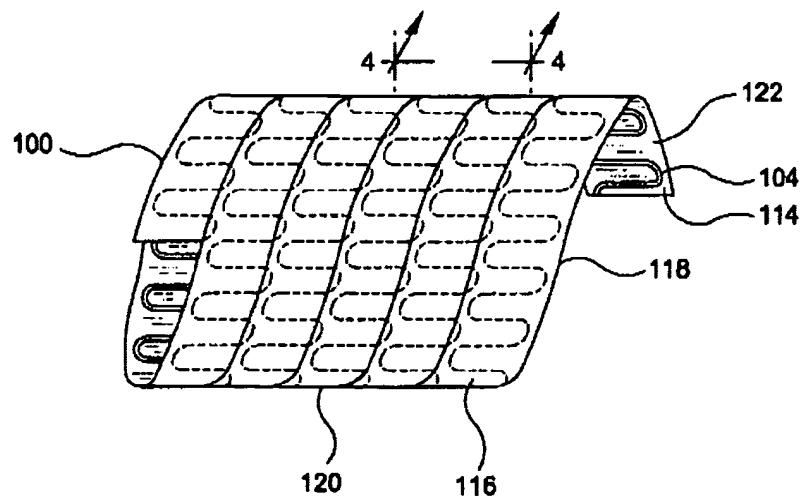
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-6,8-13,15-19,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (6364904).

Smith discloses an endoprosthesis having a longitudinal direction and a circumferential direction, said endoprosthesis comprising: a stent component having a small delivery profile and an enlarged deployed profile, said stent component having adjacent elements with space between the adjacent elements; and a graft material attached to the stent component covering the space between the adjacent stent elements to form a substantially integral and continuous luminal surface; wherein said graft material has anisotropic strength properties and is oriented so as to be weaker in the longitudinal direction than in the circumferential direction; and wherein following deployment, the endoprosthesis is adapted to be cohesively disassembled by splitting of the graft material between the adjacent elements of the stent.



Claims 3 and 44, for the purpose of examination, claims 3 and 4 are interpreted as being dependent on claim 1. The helically wrapped eptfe along with the stent would be removable at a profile less than the delivery profile and a small delivery profile.

Claim 4, it is not clear what constitutes "small delivery profile".

Claim 5, due to the helical wrapping of the eptfe tape, the disassembly of the graft would be in a helical fashion.

Claim 6, splitting the seams of the overlaps would allow the graft to be removed in a single piece.

Claims 8 and 9, the length of the disassembled graft would inherently exhibit a length greater than 100% of the original prosthetic configuration. Due to the length/diameter ratio of the graft, the expanded length of the ribbon would exceed 500% of the original length of the prosthesis.

Claim 10

Claim 11, the eptfe graft is permeable.

Claims 12 and 13, the graft of Smith is capable of being shortened.

Claim 15, the graft of Smith when removed would exhibit the same effect on the tissues as that of applicant's since applicant's device and that of Smith are essentially identical.

Claim 16, the graft material of Smith is eptfe.

Claims 17-19, see helical windings of the tape of Smith.

Claim 21, see rejection to claim 16 supra.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
3/28/2007